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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,465	03/26/2004	John B. Furness	PC25781A	1784

28523 7590 09/26/2006

PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
HUGHES, ALICIA R	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,465	FURNESS ET AL.	
	Examiner	Art Unit	
	Alicia R. Hughes	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) ~~23 and 26~~ 1-6 are subject to restriction and/or election requirement.

con. AM 9.16.06

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election

Claim 1 of the present application is generic. However, this application contains claims directed to the following patentably distinct species of the generic invention embodied in Claim 1, as outlined below:

I. Claim 2 is drawn to a method wherein "PKC is selected from the group consisting of PKCγ, PKCε, ***and*** PKCλ." (Emphasis added).

II. Claim 5 is drawn to a method wherein "said inhibitor is selected from the group consisting of staurosporine, R031-8220, ***and*** calphostin C." (Emphasis added).

III. Claim 6 is drawn to a method wherein "the patient is suffering form a disease selected from the group consisting of intestinal hypersensitivity, irritable bowel syndrome, non-ulcer dyspepsia, ***and*** other conditions that may derive from long-term changes in the behavior of enteric neurons." (Emphasis added).

The groups are independent or distinct because, Group I is drawn to enzymes while Group II is drawn to enzyme inhibitors, and Group III is drawn to a method of treating gastrointestinal diseases and disorders.

Group I is drawn to a multidomain protein genus of enzymes, protein kinase C ["PKC"] and three specie of that genus, PKCγ, PKCε, and PKCλ. Group II is drawn to a genus of PKC inhibitors and three specie of that genus - staurosporine, R031-8220, and calphostin C. Group III is drawn to a method of treating patients suffering from gastrointestinal disorders and diseases, including, but not limited to intestinal hypersensitivity, irritable bowel syndrome, and non-ulcer

dyspepsia. While the specie within each group is distinct, the groups themselves are interrelated, because Group II inhibitors can be specific to the protein kinases in Group I, and the activity between the compositions in Groups I and II combines to treat patients suffering from diseases in Group III.

The applicant is required under 35 U.S.C. 121 to elect a single disclosed species within each group for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

The applicant is advised that a reply to this requirement must include an identification of the species that is elected in each group consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Election Proper

MPEP §809.02(d) states, "[w]here only generic claims are presented, no restriction [or election] can be required except in those applications where the generic claims recite such a multiplicity of species that an unduly extensive and burdensome search is necessary." Here, the claims recite such a multiplicity of species that an unduly extensive and burdensome search would be necessary if all of the claimed species were to be examined simultaneously.

The present claims are directed to a method of treating patients who need to suppress sustained slow postsynaptic excitation by administering therapeutically effective amounts of various inhibitors. The method is drawn broadly, with generic Claim 1 being limited by: (1) a selection of one of three protein kinases; (2) a selection of one of one of three inhibitors; ***and*** (3) a selection of one of at least three diseases that are more divergent than interrelated for examination purposes.

Election is proper, because as written, the examiner would be required to simultaneously research art including, but not limited the following method(s) for treating a patient needing to suppress sustained slow postsynaptic excitation comprised of the administration of a therapeutically effective amount of: (1) PKCγ inhibited by staurosporine to treat intestinal hypersensitivity; (2) PKCγ inhibited by staurosporine to treat irritable bowel syndrome; (3) PKCγ inhibited by staurosporine to treat non-ulcer dyspepsia; (4) PKCγ inhibited by Ro 31-8220

to treat intestinal hypersensitivity; (5) PKCγ inhibited by Ro 31-8220 to treat irritable bowel syndrome; (6) PKCγ inhibited by Ro 31-8220 to treat non-ulcer dyspepsia; (7) PKCγ inhibited by Calphostin C to treat intestinal hypersensitivity; (8) PKCγ inhibited by Calphostin C to treat irritable bowel syndrome; and (9) PKCγ inhibited by Calphostin C to treat non-ulcer dyspepsia, etc. Essentially, each of the above searches could support an independent invention.

Further, as shown by the following classifications, a majority of the combinations encompassed by the present claims has acquired a separate status in the art. For example, in Group I, PKCγ, PKCε, and PKCλ are all related in that each belongs to the protein kinase C family of enzymes. PKCγ, PKCε, and PKCλ are all distinct, because each species has a different sensitivity to phospholipids, calcium, and diacylglycerol. For example, PKCγ is a classical isoenzyme that is very dependent on calcium and sensitive to diacylglycerol ["DAG"] while PKCε is a novel PKC that is calcium independent, but DAG-sensitive, and PKCλ is an atypical isoenzyme, in that it is calcium independent and DAG-insensitive.

In Group II, Staurosporine, Ro 31-8220, and Calphostin C are all related in that each is an inhibitor for the PKC family of enzymes. Staurosporine, Ro 31-8220, and Calphostin C are all distinct, too, however, because in addition to serving as an inhibitor to PKCs, these inhibitors also have varying degrees of specificity for other families of kinases. For example, staurosporine is known to have a very broad specificity for numerous protein kinases in addition to PKC, including PLA, PKG, CaMKIILYN, MLCK, S6K1, and SYK. Ro 31-8220 is a selective and ATP-competitive PKC inhibitor that is also known to inhibit growth factor-stimulated expression of MKP-1 and c-Fos, but strongly stimulate c-Jun expression and the stress-activated protein kinase JNK-1. In contrast, Calphostin C, is an inhibitor highly specific to PKC only and unlike

Staurosporine and R0 31-8220, Calphostin C requires light for activation and as a function, has been shown to inhibit cell proliferation and induce apoptosis. Unlike Calphostin C, staurosporine must be protected from the light to be effective. Finally, Staurosporine, Ro 31-8220, and Calphostin C are soluble in different solutions. For example, Staurosporine is soluble in DMSO, methanol and ethyl acetate. Ro 31-8220 is soluble in DMSO, ethanol and water. Calphostin C is soluble in DMF, DSMO, and ethanol.

In Group III, intestinal hypersensitivity, irritable bowel syndrome and non-ulcer dyspepsia is interrelated in that they are all gastrointestinal tract diseases and disorders. However, these disease and disorders are distinctive based on the symptoms associated with each and the severity of a patient's condition, with non-ulcer dyspepsia being most severe. Non-ulcer dyspepsia is a constant pain or discomfort in the upper gastrointestinal tract that may be caused by muscle spasms while irritable bowel syndrome is a disorder that comes and goes and is caused by hyperactivity of nerves that control muscles in the gastrointestinal tract. Intestinal hypersensitivity is a known cause of irritable bowel syndrome.

Because the species in each group are independent or distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, election of one species from each group for examination purposes is proper.

Inventorship Notice

Applicant is reminded that upon election of one species from each group, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR §1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-6026.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

13 September 2006
ARH

Ardin H. Marschel 9/16/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER